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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 121

RIN # 0906-AA73

Organ Procurement and Transplantation Network

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: HHS is issuing this final rule (herein referred to as “this rule”) to add vascularized composite allografts (VCAs) as specified herein to the definition of organs covered by the rules governing the operation of the Organ Procurement and Transplantation Network (OPTN) (herein referred to as the OPTN final rule). When it enacted the National Organ Transplant Act in 1984, Congress included a definition of the term organ and authorized the Secretary to expand this definition by regulation. The Secretary has previously exercised this authority and expanded the statutory definition of organ. Prior to this rule, the OPTN final rule defined covered organs as “a human kidney, liver, heart, lung, or pancreas, or intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract). Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled ‘For use in organ transplantation only.’” This rule also includes a corresponding change to the definition of human organs covered by section 301 of the National Organ Transplant Act of 1984, as amended (NOTA).

DATES: The final rule is effective July 3, 2014.

FOR FURTHER INFORMATION CONTACT: James Bowman, M.D., Medical Director, Division of Transplantation, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Room 12C-06, Rockville, Maryland 20857, or by telephone (301) 443-7577.

SUPPLEMENTARY INFORMATION: On December 16, 2011, HHS published a notice of proposed rulemaking (NPRM) in the Federal Register (76 FR 78216) to include VCAs within the definition of organs covered by the OPTN final rule and to make a corresponding change to the definition of human organs covered by section 301 of NOTA. The NPRM provided for a 60-day comment period and HHS received 29 comment letters raising a variety of issues. HHS has carefully considered all comments in developing this rule, as outlined in Section III below, presenting a summary of all major comments and Departmental responses.

I. Background

As discussed in the NPRM, the transplant community has referred to the transplants of intact vascularized body parts such as hands and faces as composite tissue allograft transplants. As tissues, these components have been under the regulatory jurisdiction of the Food and Drug Administration (FDA). For the reasons outlined in the NPRM, the Secretary believes that these components, based on their clinical characteristics, are more characteristic of organs as defined specifically in NOTA and subsequently by regulation in the case of intestines and blood vessels used in conjunction with organ transplantation. For the purpose of this regulation, these components are described as vascularized composite allografts (VCAs).

Human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient are regulated as human cells, tissues, and cellular and tissue-based products

(or HCT/Ps). FDA regulates HCT/Ps under section 361 of the Public Health Service Act (42 USC 264) and 21 CFR parts 1270 and 1271. Examples of such tissues are bone, skin, corneas, ligaments, tendons, dura mater, heart valves, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes, and semen. FDA does not regulate the transplantation of vascularized human organ transplants such as kidney, liver, heart, lung, or pancreas. FDA regulations provide that “vascularized human organs for transplantation” are not considered HCT/Ps. 21 CFR 1271.3(d)(1). HRSA oversees the transplantation of vascularized human organs.

At present, face and hand allografts, and other body parts meeting the proposed definition of VCAs, are not explicitly excluded from the definition of HCT/Ps under FDA regulations. Conversely, vascularized human organs for transplantation are excluded from FDA’s tissue regulations and are under HRSA’s purview.

On March 3, 2008, HRSA published a Request for Information (RFI) in the Federal Register (73 FR 11420) seeking feedback from stakeholders and the public as to whether VCAs should be included within the OPTN final rule’s definition of organs, and whether VCAs should be added to the definition of human organs covered by section 301 of NOTA. HRSA also sought feedback concerning the best way to specify VCAs if either definition were implemented. HRSA considered the 11 comments received in response to the RFI.

On December 16, 2011, HHS published a notice of proposed rulemaking (NPRM) in the Federal Register (76 FR 78216) to include VCAs within the definition of organs in the OPTN rule, and to make a corresponding change to the definition of human organs covered by section 301 of NOTA. The NPRM provided for a 60-day comment period and HHS received 29 comment letters raising a variety of issues. HHS has carefully considered all comments in

developing this rule, as outlined in Section III below, presenting a summary of all major comments and agency responses.

II. Summary of this Rule

Adding VCAs to the Definition of Organs Covered by the OPTN Final Rule

Based upon a review of the characteristics of VCAs and the comments submitted by the public, the Secretary believes that VCAs should be included within the definition of organs covered by the OPTN final rule (42 CFR part 121). This rule also includes a change to the definition of human organs covered by section 301 of NOTA to include VCAs. Once a body part is defined as an organ under the OPTN final rule, such body parts are excluded from the coverage of FDA regulations governing HCT/Ps, 21 CFR 1271.3(d)(1).

Pursuant to this rule, for a body part to be defined as a VCA, it must have all the following characteristics: a body part that is (1) vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation; (2) containing multiple tissue types; (3) recovered from a human donor as an anatomical/structural unit; (4) transplanted into a human recipient as an anatomical/structural unit; (5) minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement – examples of minimal manipulation include cutting, grinding, and shaping of a VCA); (6) for homologous use (i.e., the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor, *e.g.*, a hand from the donor is to be used as a hand in the recipient); (7) not combined with another article such as a device; (8) susceptible to ischemia and, therefore, only stored temporarily (*e.g.*, cold storage in preservation medium and intended

for implantation into a recipient within hours of the recovery) and not cryopreserved; and (9) susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

This definition identifies which body parts are now covered, while providing flexibility to allow other body parts to be covered as the field of VCA transplantation advances. Since the proposed rule, the word “generally” has been added to the ninth criterion for technical accuracy (e.g., in the case of identical twins where immunosuppression may not occur). A non-exclusive list of body parts that meet the definition for VCAs implemented in this rule include faces; limbs (e.g., arms, hands, fingers, legs, toes); larynges; and abdominal walls. Periodically, HRSA may publish an updated list of VCAs in the Federal Register. In addition, this definition established those body parts as organs under the OPTN final rule from other body parts that are regulated as HCT/Ps under FDA’s regulatory authority.

Additionally, a body part allocated as a VCA is intended to be used "intact" as a VCA until the transplant center receiving the VCA determines that a portion or piece of the VCA is not needed for transplantation. If portions of a VCA are not used in connection with the same transplant (e.g., leftover bone or tendons from a limb allocated as a VCA), such body parts must not be used for other purposes including transplantation in a different anatomical location in the recipient who received the VCA or in a different recipient. As explained in the NPRM, disposition of such VCA remnants would be subject to OPTN policies and state regulations. Because the definition in this rule does not identify specific VCAs by name, we are amending 42 CFR 121.4(e) to make clear that the OPTN must identify the specific body parts covered by any OPTN policy specific to VCAs. The purpose of this rule is to ensure that all OPTN members and stakeholders understand the body parts covered by OPTN policies specific to VCAs. Once

this rule goes into effect, revised 42 CFR § 121.4 (e)(3) will require the OPTN to “identify all covered body parts in any policies specific to vascularized composite allografts, defined in §121.2.” Thus, before the OPTN adopts any VCA-specific policies, the OPTN will need to list all covered body parts for clarity. This will not require a regulatory process. Under this rule, any OPTN policy that applies broadly to organs would apply to all body parts meeting the definition for VCAs unless otherwise specified.

HRSA oversees transplantation of vascularized human organs through the OPTN, which sets policies related to the procurement, transplantation, and allocation of human organs. The OPTN serves the critical role of matching donor organs to potential recipients on a national basis. Issues concerning allocation and recipient safety are similar for VCAs and for organs currently under the OPTN’s auspices. Additionally, the membership of the OPTN, which is charged with developing policies consistent with the OPTN final rule, includes professionals with expertise in the field. Therefore, the Secretary believes that the OPTN, with HRSA’s oversight, is able to effectively address issues involving the regulation of the emerging field of VCA transplantation.

The nature of the regulatory framework governing the operation of the OPTN underlies the importance of including VCAs within the definition of organs covered by the OPTN final rule. Under the OPTN final rule, the OPTN must submit proposed policies for review and approval by the Secretary (42 CFR 121.4). Upon consideration of public comments on proposed policies that are considered significant, the Secretary will determine whether to make such proposed policies enforceable in accordance with section 121.4 of the OPTN final rule. The Secretary may direct the OPTN to develop individual policies for specific body parts that are defined as VCAs in addition to OPTN policies that apply to all VCAs. Any transplant hospital

that fails to comply with any policy approved as enforceable by the Secretary under this process may be subject to the enforcement sanctions delineated in section 121.10 of the OPTN final rule, including possible termination from the Medicare and Medicaid programs.

The Secretary has the following additional authorities provided by the OPTN final rule (42 CFR 121.4(b)(2)), which she may exercise in the case of policies extending to VCAs:

The Secretary may require the OPTN Board of Directors to provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies on matters that the Secretary directs. The Secretary will refer such significant proposed policies to the Advisory Committee on Organ Transplantation (ACOT), established under 42 CFR 121.12, and publish them in the Federal Register for public comment. This is in addition to the public comment process that is engaged in by the OPTN.

The Secretary also may seek the advice of the ACOT on other proposed policies and publish them in the Federal Register for public comment.

The Secretary will determine whether proposed policies are consistent with NOTA and the OPTN final rule, taking into account the views of the ACOT and public comments. Based on this review, the Secretary may provide comments to the OPTN.

If the Secretary concludes that a proposed policy is inconsistent with NOTA or the OPTN final rule, the Secretary may direct the OPTN to revise the proposed policy consistent with the Secretary's direction. If the OPTN does not revise the proposed policy in a timely manner, or if the Secretary concludes that the proposed revision is inconsistent with NOTA or the OPTN final rule, the Secretary may take such other action as the Secretary determines appropriate, but only after additional consultation with the ACOT on the proposed action.

Also, the Secretary has the authority under the OPTN final rule (42 CFR 121.4(a)(6)) to

require the OPTN to develop policies on such matters as the Secretary directs.

By including VCAs within the OPTN final rule's definition of organs, transplants involving VCA will be subject to the requirements of the OPTN final rule. For example, entities performing transplants with covered organs must receive designation as an organ-specific designated transplant program (in this case, a designation as a VCA-specific transplant program) within an OPTN member institution. Members must comply with data submission requirements of the OPTN final rule and are subject to oversight by the OPTN for compliance with OPTN policies, OPTN bylaws, and the OPTN final rule. Members may be subject to federal enforcement actions for violations of federal regulations or enforceable policies (those approved by the Secretary of Health and Human Services) or for actions or inactions that indicate a risk to the health of patients or to public safety. Also, OPTN members can be subject to OPTN sanctions for violating OPTN bylaws and non-enforceable OPTN policies (*e.g.*, being declared a member not in good standing). The OPTN will need to devise certain policies with respect to VCAs, including allocation policies meeting the requirements set forth in the OPTN final rule.

The Secretary is legally obliged, as part of her responsibilities in administering the Medicare and Medicaid programs, to require hospitals that transplant organs to comply with the rules and requirements of the OPTN as a condition of their participation in Medicare and Medicaid. (42 U.S.C. 1320b-8(a)(1)(B)). Because VCAs currently are not included within the OPTN final rule's definition of organs, the Secretary could not currently make any VCA allocation policy enforceable. The inclusion of VCAs as covered organs under the OPTN final rule will allow the Secretary to take appropriate enforcement actions against an Organ Procurement Organization (OPO) or transplant hospital for failing to comply with any OPTN retrieval and allocation policy for VCAs, if such a policy has been approved as enforceable by

the Secretary under the process outlined above. It is necessary to ensure that VCA organ allocation, whether pertaining to isolated VCA transplants or combined/multi-organ transplants, is consistent with OPTN final rule's goals, including that of an equitable national system for organ allocation.

Even if some OPTN policies pertaining to VCA transplantation do not become approved by the Secretary as enforceable, all institutions performing VCA transplantation would be required to comply with the provisions of the OPTN final rule (including the requirement that such institutions become members of the OPTN and data submission requirements). Further, such institutions could be subject to sanctions by the OPTN for failure to comply with allocation and other OPTN policies. For example, a member may be named a member not in good standing by the OPTN for failing to comply with such a policy.

This rule includes one technical change to the regulation text originally proposed in the NPRM. One of the proposed criteria for a category of body parts to meet the definition of VCA was that it must be "susceptible to allograft rejection, requiring immunosuppression that may increase infectious disease risk to the recipient." Although this applies to all of the broad categories of these allografts (such as limb, face, abdominal wall, etc), there could be a rare situation in which the donor of a specific VCA allograft is either the identical twin of the recipient or shares such highly concordant histocompatibility matching markers in which case the recipient of the VCA allograft would not require any immunosuppression. In addition, there is potential for major advances in the field of immunologic tolerance such that clinical interventions might eliminate the susceptibility of allografts to rejection. Even though the recipient would not require immunosuppression in such situations, these categories of VCAs fall within the definition of VCAs in this notice. For this reason, the list of criteria specified for the

definition of VCAs in the amended regulation (within 42 CFR 121.2) is modified to read as follows: “(9) susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.”

Including VCAs Within the Definition of Human Organs Covered by Section 301 of NOTA

The Secretary has decided to include VCA within the definition of human organs, as covered by section 301 of NOTA, which prohibits the purchase or sale of human organs for human transplantation. This criminal prohibition provides in part that “[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. The preceding sentence does not apply with respect to human organ paired donation.” (42 U.S.C. 274e(a).) Section 301 of NOTA defines the term “human organ” to mean “the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.” (42 U.S.C. 274e(c)(1).)

As set forth by statute, the Secretary may add additional organs to the definition of human organ covered by section 301 through rulemaking to include the transplantation of additional human organs within section 301's prohibition. The Secretary has previously exercised this authority. Including VCAs within this definition of human organs may subject persons violating its terms with respect to VCAs to criminal penalties.

Through this rule, the Secretary adds VCAs to the list of human organs covered by section 301 of NOTA. The Secretary modifies 42 CFR 121.13, which includes the definition of

human organs covered by section 301 of NOTA, to include VCAs (as defined through this regulation in revised section 121.2 of the OPTN final rule). Subparts are being added to this definition to conform with Public Law 100-607, which added subparts of covered human organs to the statutory definition of human organs governed by section 301 of NOTA.

III. Comments and Responses

HHS received a total of 29 comments from the public, including transplant physicians and surgeons, health care professionals and other individuals, transplant centers, professional transplant organizations, and other non-profit organizations related to organ donation and transplantation. Of the comments received, 27 supported adding VCAs to the definition of organs covered by the OPTN final rule. The other two comments were neither favorable nor unfavorable, but did not oppose the proposal. Of the 27 supporting comments, 19 included various concerns and suggestions. All comments were considered in developing this rule. The following section presents a summary of all major issues raised in the comment letters, grouped by subject, as well as a response to such comments.

1. Use of VCA portions for non-VCA transplants in same recipient

COMMENT: A commenter suggested that portions of a VCA not required for organ transplantation (i.e., left over bone or tendons from a limb allocated from VCA) should be permitted to be used to fully reconstruct any anatomic area in that particular recipient. The commenter requested that the statement “such body parts cannot be used for transplantation into a different anatomical location in the recipient,” included in the Preamble to the NPRM, be deleted from the proposed rule. The commenter compares the use of additional tendons, nerves, vessels, fat tissue, or spinal column to the current guidelines for use of blood vessels recovered

from a donor for the express purpose of assisting in vascularization of an organ procured from the same donor and transplanted to the same recipient. The comment also envisioned that the use of donor bone marrow or fat tissue might reduce the amount of required immunosuppression and should be treated in the same manner as blood vessels for solid organ transplants.

RESPONSE: The Department does not agree with this recommended change. The Secretary appreciates the intent of the commenter to make use of available VCA portions for the benefit of patients. However, as described in the NPRM, the Department expects that portions of a VCA not used in connection with the same VCA transplant must not be used for other purposes, including transplantation in a different anatomical location in the recipient who received the VCA or in a different recipient. Disposition of VCA remnants will be subject to OPTN policies and state regulations. This provision is consistent with the current regulatory status of blood vessels recovered with organs for transplantation according to the OPTN final rule.

The term organ as defined by section 121.2 of the OPTN final rule provides that “Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled ‘For use in organ transplantation only.’” Because VCAs are being included in this definition of organs, blood vessels recovered in this way with VCAs would also be considered part of the VCA. The addition of VCAs to the OPTN final rule does not apply to the use of deceased donor bone marrow since bone marrow does not meet the criteria for VCA designation.

2. Criteria for a VCA

COMMENT: A commenter indicated that the proposed definition of organ is too broad and could cause confusion with HCT/Ps, especially whole joints and other osteoarticular allografts

(OAs) that are currently regulated as HCT/Ps by FDA. The commenter indicated that only two of the nine proposed criteria do not apply to OAs: the first criterion, the requirement for blood flow by surgical revascularization with blood vessel connection, and the ninth criterion, susceptibility to allograft rejection requiring the use of immunosuppression. The commenter suggested that for clarity and to avoid confusion this rule specifically list OAs and those other HCT/Ps currently regulated by FDA and not included as VCA organs.

RESPONSE: The Department does not agree with this comment. As indicated in the NPRM: “At the time of the RFI [2008], ... HRSA sought feedback from stakeholders and the public as to how VCAs should be defined: ... [either] (1) a broad regulatory definition describing the common features of VCAs without listing covered body parts; or (2) a definition listing body parts that would qualify as VCAs.” And the comments to the RFI suggested that VCAs should be included within the definition of organs covered under the OPTN (10 out of 11 comments supportive). In the NPRM, the Secretary proposed nine specific characteristics to establish the criteria for a body part to meet the definition of organ covered by the OPTN final rule. This approach is intended to explain to the public which body parts would be presently covered, while allowing other body parts that are transplanted to be covered as the field advances. In addition, the Department received no negative feedback in response to its request for information on adopting this approach. Therefore, VCAs are defined in this rule amendment by all nine specified criteria, not just one or several. As indicated in the NPRM, for a body part to be defined as a VCA, it must have all the nine characteristics. The examples described by the commenter (whole joint and other OAs) do not meet at least two of these criteria, so these allografts would not meet the definition of an organ according to the OPTN final rule, as revised through this regulation.

3. OPTN Policy Development

COMMENT: Two comments included suggestions regarding OPTN policy development for VCAs. They noted that VCA transplantation remains an experimental field holding great promise and should be approached carefully and thoughtfully as standards are developed to define and measure success. According to the commenters, a nationwide VCA Committee should be formed in preparation for OPTN policy approval and to provide a national dialogue. The commenter suggested that this committee should include representatives of centers that have performed a clinical VCA transplantation in the United States in addition to the major transplant and procurement societies. In addition, the commenter suggested that the committee should work with the OPTN in developing a 5-10 year timeline to incorporate VCAs within the OPTN framework.

RESPONSE: The Department agrees with the commenters that VCA transplantation is in its early phases and that the process for developing OPTN policies for VCAs (including those that create standards to define and measure success) should be approached carefully and thoughtfully with input from a broad segment of the VCA transplant community of professionals, institutions, and organizations. The OPTN final rule (section 121.4) requires the OPTN to develop policies “with the advice and interest of the OPTN membership and other interested parties.” Although the OPTN alone is responsible for establishing its policies, the development of VCA policies may include the input of other interested parties including transplantation surgeons, physicians, and other professionals, transplant centers, OPOs, and other institutions, transplant organizations, organ donor and transplant patient representation, and the public. Although there is no mechanism within the OPTN final rule to establish a formal committee outside the OPTN governance structure, the OPTN has the flexibility to gather

additional information and input from experts in the field and the public through various *ad hoc* Requests for Information and scheduled open public forums. Incorporation of VCA policies within the OPTN will be included as part of the ongoing OPTN strategic planning process.

Moreover, once this regulation goes into effect, all transplant hospitals performing VCA transplantation and participating in the Medicare or Medicaid programs will be required to be OPTN members and, as such, will be able to participate in the development of OPTN policies as members. 42 U.S.C. 1320b-8(a)(1)(B). The OPTN, in consultation with HRSA, will decide upon the specific process by which this input is obtained. As indicated in the VCA NPRM:

“The OPTN final rule does allow some flexibility specific to each organ. The OPTN sometimes fashions distinct organ-specific policies tailored to the circumstances of transplanting particular organs. For example, the training of professionals working for designated programs may vary by organ and OPTN policies with respect to disease transmission protocols and testing may diverge based on circumstances relating to particular organs. Likewise, the particular characteristics of and circumstances surrounding different types of organs lead to different OPTN allocation policies.” 76 FR at 78219.

COMMENT: One commenter requested that the Secretary provide the OPTN guidance regarding flexibility for OPTN membership to programs and groups that have not historically been focused on the field of transplantation. The commenter strongly encourages the OPTN to accept applications for medical/scientific or individual members that encompass the viewpoint and expertise of the reconstructive surgeon and their team/program as well as that of the conventional solid organ transplant team.

RESPONSE: As indicated above, the Department agrees that the process for development of OPTN policies for VCAs must be approached carefully and thoughtfully with input from a broad

segment of the VCA transplant community of professionals, institutions, and organizations. Because VCAs have not previously been included as organs under the OPTN final rule, professionals with VCA programs affiliated with the current OPTN members are not specifically identified by the OPTN as reconstructive or VCA transplant surgeons or physicians or team members within VCA programs. However, most current VCA transplant programs operate within transplant hospitals that include transplant programs for traditional organs (such as kidney, heart, liver, etc.), so the parent institutions of these VCA transplant programs are already members of the OPTN. The OPTN final rule (section 121.3 (b)(1)) requires that: “The OPTN shall admit and retain as members the following: (i) All OPOs; (ii) Transplant hospitals participating in the Medicare or Medicaid programs and; (iii) Other organizations, institutions, and individuals that have an interest in the fields of organ donation or transplantation.” Therefore, the OPTN final rule provides the flexibility requested by the commenter for OPTN membership to include appropriate VCA transplantation stakeholders.

COMMENT: One commenter expressed a preference that VCA allocation should continue at this time as a locally driven process, developing into a regional and national system as part of a long-term plan. The commenter is concerned about the effects adding VCAs will have on the current organ allocation system, such as technical issues and the multiple extensive programmatic elements that need to be developed to implement VCA allocation policies.

RESPONSE: The Department believes that development and implementation of allocation policies for VCAs by the OPTN can be complex and must be conducted in a thoughtful and deliberative manner that is widely inclusive of the broad community of VCA stakeholders and completely transparent to all. The OPTN final rule (section 121.8) emphasizes that OPTN organ allocation policies shall be based on sound medical judgment; shall seek to achieve the best use

of organs; shall be specific for each organ type; shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement; and shall not be based on the candidate's place of residence or place of listing (except to the extent required by other regulatory requirements). As stated in the Preamble to the VCA NPRM: "given the relatively small numbers of other VCAs transplanted at this time, the Secretary does not expect that the OPTN would develop allocation policies for all VCAs within a short time frame...." 76 FR at 78218. We explained the Department's expectation that the OPTN will initially create policies addressing hands and faces as these two VCAs have been the most frequently performed VCA transplant procedures in the U.S. and are the subject of extensive ongoing clinical research programs by the Departments of Defense and Veterans Affairs. The Department's position has not changed: we continue to expect that the OPTN will develop allocation policies initially for hands and faces and will wait to develop allocation policies for other organs until the field has more clinically evolved and the need arises. The OPTN utilizes organ-specific committees to discuss, draft, and propose organ-specific policies, including those related to allocation. The Department anticipates that the OPTN will establish similar committee(s) containing experts in VCA transplantation. Initially, these are likely to be committees or subcommittees for limb and/or face transplantation. The concerns and issues brought up by the commenters regarding allocation will be among the many issues discussed in detail by organ-specific VCA committee(s). Each VCA is associated with its own unique set of characteristics and clinical factors that the organ-specific committee(s) can take into consideration when developing allocation policies.

4. Impact on first person donor authorization in state registries

COMMENT: A commenter expressed concerns as to whether currently registered organ donors would be automatically “opted in” (selected) for donating VCAs (i.e., hand and/or face) or whether the organ donor authorization registry for each state would need to be changed. The commenter suggested drawing a distinction between “life extending” and “not life extending” VCAs and proposed that that each state should institute a deceased organ registry where donors could “opt in” (select specific organ designation) to elect to donate either “life extending” or “not life extending” organs (or both) while also providing donors with the option to specifically exclude the organs they do not wish to donate. Another commenter recommended that a separate authorization be established for VCA donation (presumably by states under applicable state laws).

At a meeting (February 28, 2012) of the ACOT, a committee member commented that questions had been raised about whether consent to organ donation generally (e.g., signing an organ donor card or designation in a state registry) would suffice as consent to donate a VCA. The committee member explained that, as a matter of public trust, a general consent to organ donation should not be considered adequate to constitute consent to donate a VCA.

RESPONSE: In the NPRM, the Secretary specifically requested comments regarding the potential impact of including VCAs in the definition of organs on organ donation efforts to increase participation in deceased organ donor registries, signing organ donor cards, and the general willingness of individuals to agree to be deceased organ donors. Consent to donation is governed by state law. The Uniform Anatomical Gift Act (UAGA) is a model law that addresses issues including consent to donate organs from deceased donors. The National Conference of Commissioners on Uniform State Laws have promulgated three versions of the UAGA over time (1968, 1987, and 2006), each of which included a form of first person consent (authorization),

i.e., legally honoring the decision to donate organs upon death by a person deemed competent to make such a decision. All states have enacted laws based on one of the versions of the UAGA. Most state laws on consent to organ and tissue donation are modeled on the language used in the 2006 UAGA that refers to consent to donate a “part” of the body (meaning an organ, eye, or tissue, but not the whole body). It is our understanding that most states have not clearly defined organs and have not clearly delineated which body parts qualify as organs as opposed to tissues for purposes of consent to donation. Illinois law defines “organ” to mean “a human kidney, liver, heart, lung, pancreas, small bowel, or other transplantable vascular body part as determined by the Organ Procurement and Transplantation Network, as periodically selected by the U.S. Department of Health and Human Services” (755 ILCS 50/1-10). We defer to state officials on their interpretation of state law. Putting aside Illinois law, it is our understanding that reclassifying VCAs as organs in this regulation should not affect their classification as organs, tissues, or other body parts under state laws with respect to organ and tissue donation.

The hand and face have likely been considered tissue by most (if not all) states since the first hand transplant was performed in the U.S. in 1999. VCA transplantation (whether as tissue or organ) raises the larger issue concerning the adequacy and clarity of information and education provided to prospective donors who have consented to organ and/or tissue donation or who have signed up on state donor registries. Given that VCA transplantation is an emerging field, members of the public may not understand the classification of such body parts under state law (i.e., as organs, tissues, or otherwise as body parts), if this matter has not yet been clarified by state law. Thus, we agree with the commenter that questions of public trust may arise if transparency is not kept in the forefront at every phase of the donation process. For this reason, the Secretary encourages explicit consent for VCAs from prospective donors (or next of kin) and

that such consent be as clear and meaningful as possible, and congruent with actual donor intent, especially regarding whether the consent to donate extends to VCAs specifically, and whether certain body parts should be included or excluded. Because consent to donation is governed by state law, the federal government may not resolve all of the issues related to consent for VCA donation through federal regulation. The Department believes that individual states should consider how the inclusion of face, hand, and other VCAs as organs for transplantation might impact the way that state offers the options for organ and tissue donation for its donor authorization (“first person consent”) state registry. As noted above, states establish laws that regulate first person consent for organ and tissue donation registrations. Each state has the authority to enact laws regarding the definition of organs and tissues and develop policies about whether to provide its registrants the option to specifically include or exclude the gift of specific body parts (including VCAs). Thus, states retain the ability to designate VCAs as either organ, tissue, or some other type of body part. With this rule adding VCAs to organs covered under the OPTN final rule, some states might identify a need to amend or revise current laws, regulations, policies, and/or procedures that designate how VCAs are categorized (e.g, organ, tissue, or other) within its donor authorization state registry (“first person consent”) program. For this reason, among others, this rule will be effective at 365 days following publication in order to allow sufficient time for states to accomplish these actions.

It is our understanding that OPOs must ensure that each organ (including VCAs) is recovered in accordance with the consent requirements of applicable state law. Although not always required in cases where the donor has already provided first person consent on a state registry, in the interest of full disclosure, transparency, and the public trust, it is our understanding that OPOs obtain consent or concurrence by the next of kin before proceeding

with VCA donation. Given the relatively new and transformative nature of VCA transplantation, the Secretary encourages states and stakeholders to consider best practices in informing the public about the opportunity for VCA donation and obtaining consent or authorization to donate organs and tissues generally and VCAs specifically based upon as full information as possible.

In response to the comment regarding the distinction between life saving and life enhancing organs, as indicated in the NPRM, “The Secretary does not agree with a direct demarcation between life saving organ transplants and life enhancing organ transplants for the purposes of defining organs under the OPTN final rule.” 76 FR at 78218. Until only recently, the kidney was considered life enhancing, not life saving. Nonetheless, the kidney was the first organ successfully transplanted and has always been included in the list of organs governed by NOTA and OPTN final rule. States have other mechanisms and approaches available for providing potential organ donors with first person designation options on their state registries for selecting or excluding specific body parts.

5. Impact of VCAs on cost to OPTN operations and operational efficiency

COMMENT: Six commenters expressed concerns regarding the cost of defining VCAs as organs. Five commenters stated that additional resources would be necessary for OPTN if oversight is expanded to include VCAs. Two of these commenters indicated that significant expenses would likely be incurred in the infancy of such an oversight program and that oversight of VCA transplantation could consume resources presently dedicated to the requirements of the OPTN's current mission to provide oversight programs for procurement, allocation, and transplantation of existing organs. Another commenter recommended that VCAs should be incorporated into the current OPTN fee structure with one fee for all organ types. Two commenters recommended that the OPTN seek additional and/or alternative funding mechanisms for VCA-related expenditures and that it attempt to minimize the administrative burden of adding operations related to VCA transplants.

Another commenter suggested that the Department of Health and Human Services work collaboratively with the Departments of Defense and Veterans Affairs to ensure adequate funding. One commenter expressed concern as to whether the OPTN contractor can efficiently handle the current waiting list along with new responsibilities that may result from adding VCA transplants. The commenter stated that having too many regulations may interfere with and slow down the process and affect administration of the transplant program.

RESPONSE: Appropriate funding for the effective operation of the OPTN is important for its national organ recipient matching, allocation, policymaking, and oversight responsibilities. The major costs to the OPTN to implement this rule and to incorporate VCAs within the current OPTN operations will be primarily associated with adding the relevant governance structures such as a VCA Committee. The Department does not anticipate that extensive modifications to the existing information technology infrastructure will be required. The OPTN is funded by yearly appropriations by Congress as well as a patient registration fee authorized under section 121.5(c) of the OPTN final rule (which is approved by the Secretary). The Department anticipates that its federal appropriated funds (not patient registration fees), will be used to pay for the costs to the OPTN associated with the initial implementation of VCA governance systems. The Department does not agree that this rule will result in adverse impact on OPTN operational efficiency. The small numbers of VCA transplants to date in the U.S. and the steady but slow growth in this field would suggest that the initial burden of VCAs, specifically face and limbs, is anticipated to be small and is not likely to affect the OPTN contractor's ability to handle the current waiting list along with new VCA responsibilities, nor interfere with the OPTN's ability to administer and regulate the organ transplant program.

6. Research status of VCA Transplantation

COMMENT: Three comments emphasized the current and future research aspects of VCAs. One commenter suggested continuing research during the early phases of VCA transplantation with oversight by the OPTN. Another suggested that, as an experimental field and given the small number of VCA transplants at this time, VCA transplantation should be considered as clinical research under the auspices of the OPTN. According to commenters, the field should develop in a scholarly approach, not so much to promote an academic development of this field, but rather to insure the best and most sustainable outcomes for potential patients. A third stated that VCA transplantation is not a life saving procedure, yet does require immunosuppression and rehabilitation. This can lead to allosensitization that may negatively impact future (more traditional) life saving organ transplants. A comparison was made to kidneys: after years of weighing the potential benefit of kidney transplant compared with dialysis for patients with end stage renal disease, outcomes analyses led to the now well accepted understanding that kidney transplants are in fact life saving. The commenter expressed hope that OPTN oversight would allow the creation of data sets that will assist the community in deciding who would or would not benefit from VCA transplantation.

RESPONSE: NOTA authorizes the OPTN to “carry out studies and demonstration projects for the purpose of improving procedures for organ donation procurement and allocation” (section 274(b)(2)(N)) but makes no provision for clinical organ transplantation research by the OPTN. The OPTN has no authority to direct and fund clinical research but OPTN policies allow organs to be used for nonclinical research purposes when those organs are not transplanted into human recipients. Further, NOTA does not authorize the OPTN to designate any medical procedure as experimental or investigational. Nevertheless, the Secretary understands that further clinical research will be needed to advance the field of VCA transplantation. For example, the OPTN

facilitated access to pancreatic islet cells from deceased pancreas donors under clinical research protocols supported by the National Institutes of Health (NIH). The OPTN and the Scientific Registry of Transplant Recipients (SRTR) will continue to cooperate with the transplant community and respond to requests from researchers for data needed for *bona fide* research purposes related to transplanted organs, including VCAs, in order to develop improved access and allocation for VCAs, to improve VCA candidate selection, and to identify best practices for optimal VCA transplant outcomes.

7. Risks of VCA transplantation to recipients

COMMENT: Two comments were related to the risks that VCA transplant recipients encounter and the potential risk/benefit decisions that they must make to opt for a VCA transplant. One comment stated that patients should have more time to consider the pros and cons of surgery for non-life extending VCA transplants. Given that such patients' lives are not on the line, this commenter felt that these patients are in a better situation to say "no" to surgeries they feel may be unsafe. Another commented that the short term benefits of upper limb transplantation could be observed, evaluated, and estimated in the first few years after transplantation. However, the risks of adverse events continue for the life of the patient and/or allograft. For this reason, and given the potential serious morbidity, the commenter expressed that the transplant community must continue to maximize benefit by careful patient selection and continuing strict indications for upper limb transplantation. The commenter suggested that this evaluation process be performed under research and could continue for an entire generation of upper limb transplant patients.

RESPONSE: The Department agrees that VCA transplantation poses unique organ-specific risks and that close oversight and follow up are needed for patient protections and to maximize

the optimal benefit for VCA recipients. This process will require deliberate and thorough policymaking by the OPTN to develop appropriate policies for informed consent, candidate registration, recipient follow up, and VCA transplant program requirements for staffing, infrastructure, and program policies for candidate selection criteria, pre- and post-operative patient care, follow up, and quality improvement. As noted above, NOTA makes no provision for clinical organ transplantation research by the OPTN. This would also apply to VCA organs under this regulation. Nevertheless, the Secretary understands that further clinical research will be needed to advance the field of VCA transplantation. The OPTN and the SRTR will continue to cooperate with the transplant community and respond to requests from researchers for data needed for *bona fide* research purposes related to transplanted organs including VCAs.

COMMENT: A commenter indicated that due to the potential physical and psychological impact caused by rejection of a hand or face transplant, the criteria for tissue typing compatibility based on antibody screening and cross matching must be more stringent for VCA transplants than in traditional solid organ transplants. The commenter suggested that it is necessary to obtain a history of allosensitization, including a history of number of pregnancies, number and type of transfusions, history of recent vaccinations and infections, and a history of previous organ and tissue allografts (including allogeneic heart valves and connective tissues). Additional comments include screening objectives, the frequency of screening, assignment of unacceptable antigens, sample storage, and post-transplant testing.

RESPONSE: The Department agrees that VCA transplantation presents unique aspects for the role of histocompatibility testing, tissue typing and matching, allosensitization identification and monitoring, and other potential factors that can affect the host immune response to the allograft and impact its success or failure. These issues, along with many others, will be considered as the

OPTN develops policies for incorporating specific VCA organs within its operations for candidate registration requirements, organ allocation, recipient follow up, and data collection. The OPTN Histocompatibility Committee, composed of experts in the field, considers issues relating to donor and recipient histocompatibility, organ allocation, histocompatibility testing, and histocompatibility laboratory and personnel qualifications. The goal of the Committee's work is to promote patient safety, good transplant outcomes, and best use of organs. It is the Histocompatibility Committee's responsibility to establish new and/or amend existing guidelines and policies in consideration of the unique aspects of VCA organ histocompatibility. In doing so, unique VCA histocompatibility concerns as raised by the commenter will be among the issues discussed.

COMMENT: A commenter expressed concern that as external (VCA) transplants become more common, there may be an increasing possibility of transplanting and transferring biometric identity data of the donor to the recipient.

RESPONSE: The Department believes that reclassifying VCAs as organs, rather than as HCT/Ps, does not affect the issues raised by the commenter. Whether the VCA is considered an organ (under regulatory oversight of HRSA and policy management by OPTN) or HCT/P (under regulatory oversight of FDA), transplantation of VCAs (hand and face) has been ongoing in the U.S. since 1999. These are the two most common VCAs transplanted so far and will likely remain so for the near future. A facial transplant results in a new face for the recipient as the donor's facial soft tissues are attached to the unique bone structure of the recipient. Therefore a recipient face scan is not likely to be similar to that of the donor. Upper limb transplantation does result in transferring the deceased donor's fingerprints and palm prints to the recipient. Limb transplantation has been occurring in small numbers in the U.S. since 1999. Issues related

to biometric identity authentication (potential “identity transfer”) are addressed by regulatory authorities and security and law enforcement agencies at all levels of government. These issues are also addressed by nongovernment entities responsible for their business practices and the integrity of their financial operations.

8. Waiting list criteria and potential live VCA donors

COMMENT: One commenter requested clarification as to whether veterans will be given preferred status for VCA transplantation and how this rule will affect funding or reimbursement from veteran benefits, Medicare/Medicaid, and private insurers.

RESPONSE: Wounded warriors returning from the conflicts in Iraq and Afghanistan are anticipated to constitute a significant proportion of potential candidates for limb and face transplants because of the number of limb and face injuries sustained in these battle environments. Nevertheless, organ allocation policies are not based on employment or military/veteran status, but must comply with the requirements of the OPTN final rule. The final rule does not determine benefits, coverage policies, or reimbursement amounts for organ transplantation from public or private insurers. The deceased donor (or authorized next-of-kin) has the option for directed donation to the extent permissible by applicable state and federal law.

COMMENT: One commenter questions how the VCA transplant waiting list will be categorized (i.e., by gender or race) and whether the OPTN will allow live donations or only recover a hand or face from someone who is about to die.

RESPONSE: VCAs meet the definition of organs based on this rule and are no different from any other organs previously listed under NOTA and the OPTN final rule. Each transplant center has its own selection criteria for accepting potential candidates for VCA transplant and placing them on the waiting list. The OPTN final rule provides specific allocation performance goals (42

CFR 121.8(b)), including: “Standardizing the criteria for determining suitable transplant candidates through the use of minimum criteria (expressed, to the extent possible, through objective and measurable medical criteria) for adding individuals to, and removing candidates from, organ transplant waiting lists.” The demographic categories mentioned by the commenter are not criteria utilized for placement on the organ wait list.

Live donor organs are addressed by OPTN policies. The most common are kidney and liver. Although a potential living donor may express a desire to donate a VCA, no transplant center currently provides this service. Organs are not procured in the U.S. from any person “who is about to die,” but in fact are obtained either willingly from a living donor or from a person who is already dead (deceased donor) with proper authorization.

Economic and Regulatory Impact

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety, distributive, and equity effects). In addition, under the Regulatory Flexibility Act (RFA), if a rule has a significant economic effect on a substantial number of small entities the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, costs, benefits, incentives, equity, and available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations that are significant because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the

budget, or novel legal or policy issues, require special analysis.

The Secretary has determined that minimal resources are required to implement the requirements in this rule because organizations involved (*e.g.*, OPOs and transplant hospitals) already implement related requirements for other organs in the OPTN rule (42 CFR 121.2). Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities.

The Secretary also has determined that this rule does not meet the criteria for an economically significant rule as defined by Executive Order 12866 and will have no major effect on the economy or federal expenditures. The Department has determined that this rule is not a major rule within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801. Similarly, it will not have effects on state, local, and tribal governments or on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

The provisions of this rule will not affect the following elements of family well-being: family safety, family stability, marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning, disposable income, or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999.

As stated above, this rule modifies the regulations governing the OPTN and section 301 of NOTA based on legal authority.

Impact of the New Rule

This rule has the effect of including VCAs within the ambit of the regulations governing the operation of the OPTN, and would include transplanted human VCAs within the prohibition set forth at section 301 of NOTA. This rule authorizes the Secretary to take enforcement actions against entities violating OPTN policies pertaining to the transplantation of VCAs once such policies are approved as enforceable by the Secretary. Even if the Secretary does not approve such policies as enforceable, OPTN members may be subject to enforcement actions by the OPTN for violations of OPTN policies extending to VCAs. OPTN members will be required to comply with requirements set forth in the OPTN final rule, including those pertaining to data submission, as applied to VCAs. Finally, individuals violating section 301 of NOTA with respect to VCA transplants may be subject to criminal penalties.

Paperwork Reduction Act of 1995

Prior to the amendments made through this regulation, the OPTN final rule authorized information collection activities with respect to “organs” as defined in 42 CFR 121.2. See generally 42 CFR 121.11. Because this regulation expands the definition of organs to encompass VCAs, the OPTN final rule’s existing information collection authorities will now extend to information concerning VCAs. The current data collection requirements in the OPTN final rule approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 and assigned control numbers OMB No. 0915-0157 (for organ donors, candidates, and recipients) and OMB No. 0915-0184 (for OPTN membership application data) will be impacted by this rule because much of the information collected on these forms will now be collected with respect to VCA donors, candidates, and recipients, as well as VCA transplant programs. The new collections, reporting and disclosure activities (listed in the table below) will be submitted to

OMB for approval in accordance with OMB requirements.

Membership in the OPTN is determined by submission of application materials to the OPTN demonstrating that the applicant meets all required criteria for membership and will agree to comply with all applicable provisions of NOTA. 42 U.S.C. 273 *et seq.* Section 1138(a)(1)(B) of the Social Security Act, as amended, 42 U.S.C. 1320b-8(a)(1)(B), requires that hospitals in which transplants are performed by members of, and abide by the rules and requirements (as approved by the Secretary of HHS) of the OPTN as a condition of participation in Medicare and Medicaid for the hospital. Section 1138 contains a similar provision for the OPOs and makes membership in the OPTN and compliance with its operating rules and requirements (as approved by the Secretary of HHS), including those relating to data collection, mandatory for all transplant programs and OPOs. The information is used predominantly to match donor organs with recipients, to monitor compliance of member organizations with OPTN policies and requirements to guide organ allocation policy development, and to report periodically on the clinical and scientific status of organ donation and transplantation in this country.

The currently-approved data collections include worksheets and reporting burden for organs and describe respondents as non-profit institutions and small organizations, which would be the same for this rule. The title, description, and respondent description of all information collections relating to VCAs are shown (see table below) with similar estimates of annual reporting and record keeping burden as with other organs previously approved in the OPTN final rule.

Currently there are approximately 12 hand, 4 face, and 1 abdominal wall transplant programs in the U.S., although only 9 have actually performed a clinical transplant operation to date. The current rate of VCA transplants is less than 10 a year for hands and less than one a

year for faces and abdominal walls). For reporting calculations (below), we have projected a total of 10 VCA transplant programs, each registering 2 candidates a year to the waiting list and each program performing 1 transplant procedure a year. The data burden calculation (see table below) assumes that data associated with entering deceased donor information is already accounted in the current OMB approved data collection forms and does not represent additional data collection burden resulting from this final rule. Specifically, it is reasonable to assume that any donor that would be considered a VCA donor is also considered to be a donor for other organs already covered by this rule. The hourly rate used for calculation of total burden cost to respondents is the average hourly wage for a transplant data coordinator (\$26.00). This rate reflects the median annual salary and benefits for a Data Control Clerk II (www.salary.com). The total annual respondent burden hours (42.5) represents 4.2 hours (\$109.20) per respondent.

Title: Organ Procurement and Transplantation Network.

Description: Information will be collected from transplant hospitals, OPOs, and histocompatibility laboratories predominantly for the purpose of matching donor VCAs with potential recipients, monitoring compliance of member organizations with system rules, conducting statistical analyses, and developing policies relating to organ procurement and transplantation.

The practical utility of the data collection is further enhanced by requirements that the OPTN must report a variety of data to the Secretary, including data on performance by organ and status category, including program-specific data, OPO-specific data, data by program size, and data aggregated by organ procurement area, OPTN region, the nation as a whole, and other geographic areas (42 CFR 121.8(c)(3)). The OPTN must also transmit proposed allocation

policies and performance indicators, which will be used to assess the likely effects of policy changes and to ensure that the proposed policies are consistent with the OPTN final rule.

The OPTN and Scientific Registry must make available to the public timely and accurate information concerning the performance of transplant programs, and must respond to requests from the public for data needed for *bona fide* research or analysis purposes or to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes (42 CFR 121.11(b)(1)(iv) and 42 CFR 121.11(b)(1)(v) and 42 CFR 121.11(b)(1)(vi)).

The OPTN must provide to each member OPO and transplant hospital the plans and procedures for reviewing applications and for monitoring compliance with these rules and OPTN policies. The OPTN must also report to the Secretary on OPOs and transplant hospitals that may not be in compliance with these rules or OPTN policies, and on their progress toward compliance.

The OPTN and Scientific Registry are required to maintain and manage the information on candidates, donors and recipients.

Description of Respondents: Non-profit institutions and small organizations.

The estimated annual reporting burden is as follows:

Section	Form	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours (cost)
121.5(b)	VCA Candidate	10	2	20	0.30	6 (\$156)

	Registration					
121.6(c)	Submitting criteria for VCA acceptance (reporting)	10	1	10	0.5	5 (\$130)
121.6(c)	Sending criteria to OPOs (disclosure)	10	1	10	0.5	5 (\$130)
121.7(b)(4)	Reasons for Refusal	10	1	10	0.1	1 (\$26)
121.9(b)	Designated transplant program requirements	10	1	10	2	20 (\$520)
121.11(b)(2)	VCA Registration	10	1	10	0.25	2.5
121.11(b)(2)	VCA Follow up	10	1	10	0.20	2 (\$52)
121.11(b)(2)	Post- transplant	10	1	10	0.08	1 (\$26)

	malignancy					
Total		139	9	90	14.6	42.5 (\$1105)

List of Subjects in 42 CFR Part 121

Health care, Hospitals, Organ transplantation, Reporting and record keeping requirements.

Dated: February 8, 2013

Mary Wakefield, Ph.D., R.N.,

Administrator,

Health Resources and Services Administration.

Approved: February 14, 2013

Kathleen Sebelius,

Secretary.

Accordingly, 42 CFR part 121 is amended as set forth below:

PART 121 - ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

1. The authority citation for part 121 continues to read as follows:

AUTHORITY: Sections 215, 371-376 of the Public Health Service Act (42 U.S.C. 216, 273-274d); sections 1102, 1106, 1138 and 1871 of the Social Security Act (42 U.S.C. 1302, 1306,

1320b-8 and 1395hh); and section 301 of the National Organ Transplant Act, as amended (42 U.S.C. 274e).

2. Amend §121.2 by revising the definition for “Organ” and adding a definition for Vascularized composite allograft” to read as follows:

§ 121.2 Definitions.

* * * * *

Organ means a human kidney, liver, heart, lung, pancreas, intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract) or vascularized composite allograft (defined in this section). Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled “For use in organ transplantation only.”

* * * * *

Vascularized composite allograft means a body part:

- (1) That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation;
- (2) Containing multiple tissue types;
- (3) Recovered from a human donor as an anatomical/structural unit;
- (4) Transplanted into a human recipient as an anatomical/structural unit;
- (5) Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ’s utility for reconstruction, repair, or replacement);
- (6) For homologous use (the replacement or supplementation of a recipient's organ with an

organ that performs the same basic function or functions in the recipient as in the donor);

(7) Not combined with another article such as a device;

(8) Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; and

(9) Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

* * * * *

3. In §121.4, add paragraph (e)(3) to read as follows:

§ 121.4 OPTN policies: Secretarial review and appeals.

* * * * *

(e) * * *

(3) Identify all covered body parts in any policies specific to vascularized composite allografts, defined in §121.2.

4. Revise §121.13 to read as follows:

§121.13 Definition of Human Organ Under section 301 of the National Organ Transplant Act of 1984, as amended.

Human organ, as covered by section 301 of the National Organ Transplant Act of 1984, as amended, means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin, intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract) or any vascularized composite allograft defined in §121.2. It also means any subpart thereof, including that derived from a fetus.